when implanted. The foam tissue scaffold partially encapsulates the fixation component, as discussed in the specification and as disclosed in the figures, and thus provides fixed attachment of the porous tissue scaffold to the fixation component. No other means are required to maintain attachment of the scaffold component to the fixation component.

Gresser discloses an interbody spinal fusion device for use as spacers in spinal fixation. The device may comprise a plurality of peripheral voids, or a central void space, which may be filled with a grafting material for facilitating bony development and/or spinal fusion, as well as resorption of the device by the body (0008). In particular, periosteum cells may be incorporated into a foam and placed into the voids (0014). Figures 4A and 4B depict a device in the shape of a threaded screw. Cylindrical holes 43 and 44 are provided through the body of the device orthogonal to each other and to the screw axis, although the purpose for such holes is not disclosed. A cylindrical hole 45 is provided coaxially with the axis. Again, the purpose of the hole is not disclosed. However, as noted above, it is understood that a foam containing cells may be placed "inside" of the device via the cylindrical holes. Slots 46 and 48 serve to position and retain a tool for screwing the device into place.

Applicants respectfully submit that, according to the specification of Gresser, the main body of the device cannot comprise foam, as indicated by the Office Action, and thus cannot provide a foam tissue scaffold component. At paragraph 0037 of Gresser, it is noted that mechanical properties of the device, e.g. the main body of FIG 4A, should match those of the cancellous bone of the vertebrae in regard to proportional limit stress, compression at proportion limits, etc. At paragraph 0043 it is noted that the spinal fusion device must maintain significant structural rigidity for 6-12 months. It is respectfully submitted that foam scaffolds would neither provide mechanical properties matching those of cancellous bone nor would they provide structure rigidity for 6-12 months, each required by Gresser. Applicants respectfully submit that to modify Gresser by forming the main body of the spinal fusion device out of foam, as suggested by the Office Action, would render Gresser inoperable for its intended use, that being spinal fusion, which it is respectfully submitted is not permitted.

Nor is the device of Gresser (Fig 4A) partially encapsulated by a foam tissue scaffold component. Gresser notes that a foam scaffold containing cells may be placed

"within" the spinal fusion device. However, the foam scaffold neither partially encapsulates the main body of Fig 4A, nor is it fixedly attached to the device by such encapsulation. Based on the foregoing, Applicants respectfully submit that Gresser fails to disclose or suggest a tissue scaffold implant device comprising a foam tissue scaffold component and a fixation component partially encapsulated by the tissue scaffold component, whereby the foam scaffold is fixedly attached to the fixation component. Accordingly, Applicants respectfully request that the rejection of claims 1-5, 7-11 13 and 14 over Gresser be withdrawn.

Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Melican et al. US 2002/0120348. Applicants respectfully traverse.

The Office Action indicates that Melican comprises fixation component 16 as shown in Fig 3 of Melican containing anchor means such as sutures or staples. Applicants respectfully disagree. In fact, structure 16 is a barrier layer and does not comprise any means for anchoring the implant upon implantation. The Office Action also indicates that the reinforcement layer of Melican may serve as the fixation component. Applicants respectfully disagree. The Office Action states that the fibrous layer "may" include anchors such as non-absorbable staples. In fact, the reinforcement layer does not comprise means for anchoring the scaffold upon implantation. While Melican does disclose that fixation devices, e.g. sutures or staples, may be employed with reinforced tissue implants disclose therein, Applicants respectfully submit that devices disclosed in Melican do not include a tissue scaffold support and anchor means in and of themselves.

Based on the foregoing, Applicants respectfully submit that Melican fails to anticipate any of claims 1-14 and respectfully request that the rejection under 35 U.S.C. 102(e) be withdrawn.

Applicants respectfully submit that the standard for anticipation is strict identify. Each and every claim element must be disclosed or inherent in the prior art. Applicants respectfully submit that neither Gresser nor Melican disclose, or suggest for that matter, an implantation device that includes both a foam tissue scaffold component and a fixation component fixedly attached to the foam tissue component, where the fixation component includes both a tissue scaffold support element and a means for anchoring the implant device upon implantation, wherein the foam tissue scaffold partially encapsulates the

fixation component, thereby providing the fixed attachment of the tissue scaffold to the fixation component.

Based on all of the foregoing, Applicants respectfully submit that claims 1-14 are patentable and earnestly request a Notice of Allowance to that affect. Applicants' representative would welcome the opportunity to discuss the Office Action and Response with the Examiner and can be reached at 732-524-6201. Applicants are filing a Notice of Appeal herewith.

Respectfully submitted

William K. Wissing
Attorney for Applicants
Registration No. 34,757

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
732.524.6201